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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,923	01/09/2002	Kevin J. McKernan	12130-007001	4511
26161	7590	11/12/2004		
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			EXAMINER NAFF, DAVID M	
			ART UNIT 1651	PAPER NUMBER
DATE MAILED: 11/12/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,923

Applicant(s)

MCKERNAN, KEVIN J.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 35-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/7/02</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

In a response of 8/23/04 to a restriction requirement of 6/22/04, applicant elected claims 1-34 without traverse.

Claims 35-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/23/04.

Claims 1-34 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method as required by claim 1 when the first reagent is a single reagent containing the precipitating reagent, the carrier and a reagent component that causes cell lysis, and the method of claim 15 when the second reagent is a single reagent containing the precipitating reagent and the carrier, does not reasonably provide enablement for the substantially different methods

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encompassed by the present claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification has enabled obtaining the disclosed results only when performing a method as required by claims 1 and 15 when using a single reagent as the first and second reagents to simplify and reduce the number of steps as disclosed in the specification (page 2, lines 8-11; paragraph bridging pages 10 and 11; page 21, lines 19-20; and page 31, lines 11-13 and 23-24). Additionally, claims 32-34 fail to contain sufficient steps to result in an isolated nucleic acid as described in the specification and as required in the preamble of claim 34. The claimed method must be commensurate in scope with the method described in the specification that produced the advantageous results disclosed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

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out and distinctly claim the subject matter which applicant regards as the invention.

The recitations "simultaneously adding to the cell one or more reagent components collectively referred to as a first reagent" (bridging lines 4 and 5 of claim 1) and "simultaneously adding to the second mixture one or more reagent components collectively referred to as a second reagent" (bridging line 3 and 4 of claim 15) are uncertain as to meaning and scope. There cannot be simultaneous addition when only one reagent component is present as is encompassed by reciting "one or more reagent components". Additionally, claims 1 and 15 require a precipitating reagent and a carrier, and these are two reagent components that will preclude one reagent component. It is unclear in claims 1 and 15 as to which reagent components are being added simultaneously, and which reagent components are being collectively referred to as first and second reagents. This also applies to claims 32 and 34 for the same type of reasons.

Claims 1, 15, 32 and 34 are unclear as to the relationship of the "one or more reagent components" to the precipitating reagent and the solid phase carrier. Are the precipitating reagent and the carrier reagent components? If they are reagent

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components, the claims should require a precipitating reagent component and a solid phase carrier reagent component.

In line 6 of claim 1, "reagent is formulated to cause lysis of the cell" and in claim 32, line 3, "first reagent causes lysis of the cell" are unclear as to whether "formulated" and "reagent causes lysis" are requiring a reagent component in addition to the precipitating reagent and the carrier.

In dependent claims 13 and 28, the recitation "reagent consists of one reagent component" is uncertain as to how claims 1 and 15 are being further limited. The first reagent of claim 1 and second reagent of claim 15 have more than one component, i.e. a precipitating reagent and a carrier. Therefore, the first and second reagents cannot be one component, unless components are omitted. If components are omitted, it is uncertain how the methods are performed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the

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United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32-34 are rejected under 35 U.S.C. 102(e) as being anticipated by McKernan et al (6,534,262 B1).

The claims are drawn to a method of isolating a nucleic acid molecule from a cell by adding to the cell, one or more reagent components collectively referred to as a first reagent wherein the first reagent causes cell lysis and comprises a nucleic acid precipitating reagent and a solid phase carrier having a surface that reversibly binds a nucleic acid molecule of the cell. The solid phase containing a first species of nucleic acid can be removed to form a first mixture. To the first mixture, can be added reagent components collectively referred to as a second reagent containing a nucleic acid precipitating reagent and a solid phase carrier that reversibly binds a nucleic acid of the cell.

McKernan et al disclose a method of selectively isolating a target nucleic acid species that involves using reagents that include a cell lysis reagent, a nucleic acid precipitating reagent and a carrier that reversibly binds the nucleic acid, removing the carrier to produce a second mixture, eluting nucleic acid from the carrier, adding second reagents including a nucleic acid precipitating reagent and a carrier that

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reversibly binds another nucleic acid, removing the carrier containing the another nucleic acid, and eluting the other nucleic acid.

The method of McKernan et al is the same as presently claimed. The present claims collectively referring to reagent components as first and second reagents does not make the claimed method different from the method of McKernan et al since reagents used by McKernan et al can be collectively referred to as first and second reagents. Collectively referring to reagents as claimed does not require different steps from the steps of McKernan et al, and the present claims encompass a method as described by McKernan et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-19 and 21-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKernan et al in view of Boom et al (5,234,809).

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Claims 32-34 are described above.

Claims 1-3, 5-19 and 21-31 require a method as set forth above, and additionally require simultaneously adding the one or more reagent components.

McKernan et al is described above.

Boom et al disclose isolating nucleic acids by a process that involves a one-step procedure (col 3, line 10) of adding an admixture of suspended silica particles and buffered GuSCN to cells (col 4, lines 9-15). The GuSCN lysis the cells to release nucleic acids, and the nucleic acids are bound to the silica particles. After washing the nucleic acids are eluted from the silica particles (col 4, lines 28-31).

It would have been obvious to add the cell lysis reagent, precipitating reagent and carrier simultaneously to cells in the nucleic acid isolating method of McKernan et al as suggested by Boom et al adding a lysis reagent (GuSCN) and a carrier simultaneously in a one-step procedure to cells in a method of isolating nucleic acids. Combining reagents before addition would have been expected to enable adding all reagents in a single step rather than in multiple steps, and this combining would have been obvious. The conditions of dependent are the same type of conditions disclosed by McKernan et al, and would have been obvious.

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Claim Rejections - 35 USC § 103

Claims 4 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-3, 5-19 and 21-34 above, and further in view of Alvarez et al (5,443,989).

The claims require a multisample transfer device for adding the first and second reagents.

McKernan et al is described above. In addition, McKernan et al disclose that the method can be used to simultaneously process 96 individual samples (col 17, lines 25-30).

Alvarez et al disclose using automated multisample applicators to allow application of up to 72 different samples at variable volumes and application speed when assaying for dipalmitoyl phosphatidyl choline (DPPC) (col 6, lines 4 and 33-36).

When simultaneously adding reagents in McKernan et al as suggested by Boom et al as set forth above and simultaneously processing 96 samples as disclosed by McKernan et al, it would have been obvious to use automated multisample applicators as disclosed by Alvarez et al to facilitate sample processing.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-19 and 21-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,534,262 B1 in view of Boom et al.

The claims of the patent (McKernan et al) require a method of isolating nucleic acids as set forth above when describing McKernan et al.

It would have been obvious to add the cell lysis reagent, precipitating reagent and carrier simultaneously to cells in the nucleic acid isolating method of the patent claims as suggested by Boom et al adding a lysis reagent (GuSCN) and a carrier simultaneously in a one-step procedure to cells in a method of isolating nucleic acids as set forth above when applying Boom et al.

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Double Patenting

Claims 4 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,534,262 B1 in view of Boom et al as applied to claims 1-3, 5-19 and 21-34 above, and in further view of Alvarez et al.

Alvarez et al would have suggested using a multisample transfer device in the claimed method of the patent to enable processing a large number of samples when adding reagents simultaneously as set forth above.

Double Patenting

Claims 1-3, 5-19 and 21-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 10/346,714 or claims 1-33 of copending Application No. 10/406,141 in view of Boom et al.

The claims of the applications require a method of isolating nucleic acids using reagents as used by McKernan et al as set forth above.

It would have been obvious to add the cell lysis reagent, precipitating reagent and carrier simultaneously to cells in the nucleic acid isolating method of the application claims as suggested by Boom et al adding a lysis reagent (GuSCN) and a

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carrier simultaneously in a one-step procedure to cells in a method of isolating nucleic acids as set forth above when applying Boom et al.

This is a provisional obviousness-type double patenting rejection.

Double Patenting

Claims 4 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 10/346,714 or claims 1-33 of copending Application No. 10/406,141 in view of Boom et al as applied to claims 1-3, 5-19 and 21-34 above, and in further view of Alvarez et al for the type of reasons set forth above when applying Alvarez et al.

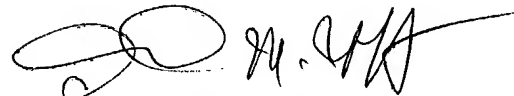
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'D. M. Naff', with a large, stylized loop at the beginning.

David M. Naff
Primary Examiner
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DMN
11/9/04